IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF SOUTH CAROLINA
Charleston Division

DEREK CLEMENTS, *et al.*,	)	
	)	
Plaintiffs	)	
	)	
v.	)	Civil Action No. 2:22-cv-02069-RMG
	)	
LLOYD J. AUSTIN, III,	)	
	)	
Defendant.	)	
	)	

PLAINTIFFS' REPLY IN SUPPORT OF THEIR SECOND MOTION FOR A PRELIMINARY INJUNCTION

Plaintiffs, by and through counsel, respectfully submit this Reply in Support of their Second Motion for a Preliminary Injunction pursuant to Fed. R. Civ. P. 65 and LCvR 65.01.

Defendant Secretary Lloyd J. Austin, III violated federal statutory law in August 2021 by ordering all service members to receive a Covid-19 vaccination, despite there being no available stock of licensed vaccines at the time of the order. In short, DoD mandated compliance with an order that could not be carried out. This on its own constitutes arbitrary and capricious decision making under the Administrative Procedures Act ("APA")—a standard of review that requires the Court to look at the Agency's reason and rationale at the time the action was taken, and not on a subsequent, post-hoc administrative record. This standard forms the basis for Plaintiffs' claims and their arguments in support of their Second Motion for a Preliminary Injunction.

In response, Defendant attacks Plaintiffs' motion on two main grounds—(1) that the Court cannot touch this case, be it through justiciability, standing, ripeness, or propriety; and (2) that the substance of Plaintiffs' claims are unlikely to succeed.

Defendant is simply wrong on both grounds. As acknowledged by Defendant, federal courts have consistently adjudicated claims that are virtually identical to Plaintiffs' with regards to challenging military orders that violate federal law and service regulations, including in cases addressing vaccine and service-wide medical decisions. *See, e.g.*, *Doe v. Rumsfeld*, 341 F. Supp. 2d 1, 17 (D.D.C. 2004); *Roe v. Dep't of Defense*, 947 F.3d 207, 218-220 (4th Cir. 2020).

Moreover, Plaintiffs demonstrate a likelihood of success on their claims relating to the status of the vaccine *at the time* of Defendant's order, and particularly given Defendants' arbitrary and capricious decision-making with respect to its own regulations.

For these reasons, Plaintiffs ask the Court to preliminarily enjoin enforcement of the DoD COVID-19 mandate, to include all disciplinary proceedings for those who refuse to follow the unlawful order. This preliminary injunction would inherently require all Plaintiffs to be treated the same as their vaccinated counterparts (treatment which is now consistent with the Center for Disease Control and Prevention ("CDC") guidance[1]) pending outcome of this litigation.

ARGUMENT

I. Plaintiffs' Claims Are Justiciable and Are Appropriately Before this Court

Plaintiffs' do not challenge DoD's ability to vaccinate its service members. Defendant is attempting to generate a smokescreen by framing this case as an infringement on the military's discretion and need to maintain a mission-ready force in the face of a deadly disease. But Plaintiffs are bringing an APA case with a simple, straightforward premise: did DoD comply with federal statues and its own regulations when issuing the vaccine mandate? This question is

[1] Ctrs. For Disease Control & Prevention, CDC streamlines COVID-19 guidance to help the public better protect themselves and understand their risk, https://www.cdc.gov/media/releases/2022/p0811-covid-guidance.html (last visited Aug. 15, 2022).

squarely within the purview of the Court to answer, and Plaintiffs are suitable candidates for raising it.

As an initial matter, review of military decisions of this kind are clearly proper and justiciable. *Roe*, 947 F.3d at 218-220 (noting the application of the APA to the military).[2] And Plaintiffs, as service members directly affected by an unlawful order, have sufficient standing to challenge it.[3] *Id.*

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[2] This Circuit has never had reservations about "directing the military to comply with its own regulations where it has been shown that a regulation was not followed, and there has been a prima facie showing that a member of the military has been prejudiced thereby," to include cases of medical compliance. *Bluth v. Laird*, 435 F.2d 1065, 1071 (4th Cir. 1970); *see also Roe*, 947 F.3d at 218-220 (finding that individualized assessment was required in discharging servicemembers who were HIV positive); *United States ex rel. Brooks v. Clifford*, 409 F.2d 700 (4th Cir. 1969). "[W]hen the sovereign has established rules to govern its own conduct it will be held to the self-imposed limitations on its own authority, departure from which denies procedural due process of law." *Bluth*, 435 F.2d at 1071 (citing *United States v. Heffner*, 420 F.2d 809 (4th Cir. 1969)). "[I]n exercising its discretion, the military *will* be held to the positive commands it has imposed on itself as to what procedures and steps are to be followed in exercising its discretion." *Id.* (emphasis added).

[3]Analysis on this issue in other courts is particularly persuasive. *See, e.g.*, *Creaghan v. Austin*, No. CV 22-0981 (CKK), 2022 WL 1500544, at *5 (D.D.C. May 12, 2022).

> First, the Government argues that Plaintiff lacks standing to challenge the denial of her requested religious accommodation because separation proceedings have not yet begun. Not so.
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> To receive a preliminary injunction, the moving "party must show, among other things, a 'substantial likelihood of success on the merits.'" *Food & Water Watch, Inc. v. Vilsack*, 808 F.3d 905, 913 (D.C. Cir. 2015). "The merits on which plaintiff must show likelihood of success encompass not only substantive theories but also establishment of jurisdiction," including Article III standing. *See Elec. Priv. Info. Ctr. v. Dep't of Com.*, 928 F.3d 95, 104 (D.C. Cir. 2019). To show standing, a plaintiff must show an "injury-in-fact that is 'imminent' or 'certainly impending.'" *Am. Petrol. Inst. v. EPA*, 683 F.3d 382, 386 (D.C. Cir. 2012).
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> Defendants seem to construe the alleged injury as separation proceedings or other adverse action predicated upon the denial of Plaintiff's accommodation request. Plaintiff, however, relies on, the deprivation of a statutory or constitutional right as an "injury-in-fact" triggering Article III jurisdiction. *See Warth v. Seldin*, 422 U.S. 490, 500, 95 S.Ct.

Moreover, as a direct consequence of this order, Plaintiffs are facing all-but-certain separation regardless of where they currently are in the disciplinary/discharge process. Plaintiffs need not exhaust futile remedies before bringing a claim to this court. *See Roe v. Shanahan*, 359 F. Supp. 3d 382, 403 (E.D. Va. 2019) (finding exhaustion in a military case, because the correction boards "cannot adjudicate a claim that the [military's] policies and regulations themselves are unconstitutional or otherwise unlawful) (referencing *Nationsbank Corp. v. Herman*, 174 F.3d 424, 429 (4th Cir. 1999)); *McDonald v. Centra, Inc.*, 946 F.2d 1059, 1063 (4th Cir. 1991); *see also Shalala v. Ill. Council on Long Term Care, Inc.*, 529 U.S. 1, 12-13, 120 S.Ct. 1084, 146 L.Ed.2d 1 (2000). Accordingly, Plaintiffs have pursued the available options to receive exemptions for the vaccines, to no avail, as these have been (predictably) denied as a matter of routine. The military has made no qualms about its intent to discharge unvaccinated individuals, meaning that Plaintiffs are all but certain to be discharged – indeed it is for this reason that Defendant defends the mandate, arguing that unvaccinated individuals are a threat that needs removal. There is nothing that stands in between Plaintiffs' discharge and retention other than this court case.

It appears based on their arguments, that Defendants are operating under the belief that Plaintiffs would only be able to challenge an unlawful order once they are completely through with every arcane administrative process that might be available to them via the DoD and their respective service, despite the clear pre-determined outcomes. As the U.S. Coast Guard

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> 2197, 45 L.Ed.2d 343 (1975). Insofar as Plaintiff has exhausted her administrative remedies to receive a religious exemption from COVID-19 vaccination, the Court agrees that Plaintiff has demonstrated a likelihood of success in demonstrating that she has standing to challenge that denial.

Id.

Academy ("USCGA") has clearly demonstrated with its appalling treatment of the cadets, the administrative processes that Plaintiffs, including the U.S. Military Academy ("USMA") cadets, are subject to will undoubtably lead to separation and/or disenrollment. Exhibits 5, 13-14.

Additionally, the current status of the various service members who may or may not be subject to discharge or expulsion because of a pending preliminary injunction that could be revoked anytime is irrelevant to the issue of success on the merits in this case. In short, the focus of this case is whether the vaccine used by Defendant was fully licensed and available at the time Defendant issued his order to vaccinate the entire military force. This issue is ripe for evaluation, and is properly raised in this forum, at this time.

II. Plaintiffs Are Likely to Succeed on the Merits, Because DoD's Mandate Order was Enacted Despite A Complete Lack of Licensed Vaccine Stock at the Time of its Enactment

A. At the time of the order, there was no available licensed vaccine

United States Food and Drug Administration ("FDA")-licensed COMIRNATY was not available in the United States at the time the mandate was issued. Defendants effectively admit as much in their Opposition when they assert that one could not even begin *ordering* "COMIRNATY labeled" vaccine until May 20, 2022—9 *months* after the DoD mandate was issued. Def. Resp. at 17. ("On May 20, 2022, Pfizer-BioNTech's COMIRNATY-labeled vaccine became available for ordering."). Nor was there any interchangeable product that satisfied Defendant's obligation under 10 U.S.C. § 1107a. The FDA's Purple Book, an online compendium of all licensed vaccines and drugs available in the United States, shows that there is

no substitute or interchangeable vaccine for COMIRNATY, including the Pfizer-BioNTech EUA vaccine.[4] Exhibit 22.

This admission, coupled with the evidence from the FDA's own publication, is clear proof that Plaintiffs' claim is likely to succeed on the merits, because it means that DoD issued an order that could only have one of two outcomes, both of which violate the rights and statutory protections offered to service members. One, DoD intended that all service members would have to submit to an EUA vaccine, in direct contradiction to federal statute. Or two, DoD intended that all service members would have to comply with an impossible order to take a vaccine that is unavailable.[5] It is clear that DoD intended the first outcome, based on its flimsy attempts to characterize EUA vaccines as licensed vaccines, in the hope that it could avoid recompense.

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[4] FDA U.S. Food & Drug Administration, Purple Book Database of Licensed Biological Products, https://purplebooksearch.fda.gov/results?query=COVID-19%20Vaccine,%20mRNA&title=Comirnaty (last visited August 31, 2022).

[5] The *Croker v. Austin* court frames both the position put forward by DoD and the critical problem with DoD's position particularly well, stating:

> Defendant attempts to argue that DoD's mandate only applies to licensed products, and therefore does not violate § 1107a, even if Defendant is found to be incorrect in asserting that EUA vaccines were also licensed. *See, e.g.*, DoD mandate memorandum ("Mandatory vaccination against COVID-19 will only use COVID-19 vaccines that receive full licensure from the [FDA] in accordance with FDA-approved labeling and guidance."); and ECF No. 1-7 at 11 (Air Force guidance) ("Only an FDA-licensed vaccine may be mandated ...."). The plaintiffs present a facial challenge, ECF No. 33 at 10 ("Plaintiffs' claims are facial challenges to a generally applicable military regulation ...."), and on its face, the mandate does not require anyone to take an EUA vaccine.
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> Notably, though, Plaintiffs have shown that the DoD is requiring injections from vials not labeled "Comirnaty." Indeed, defense counsel could not even say whether vaccines labeled "Comirnaty" exist at all. ECF No. 45 at 48:5-7. (Although the DoD's response said it had an adequate Comirnaty supply, it later clarified that it was mandating vaccines from EUA-labeled vials. *See id.* at 46:22-47:3.) In the DoD's view, this is fine because the contents of EUA-labeled vials are chemically identical to the contents of vials labeled "Comirnaty" (if there are any such vials). According to the DoD's argument, this means servicemembers are not required to accept "a product authorized for emergency use." 10

In conducting an APA review, the Court must "consider the record made before the agency at the time the agency acted," so "post-hoc rationalizations … have 'traditionally been found to be an inadequate basis for review.'" *Dow AgroSciences LLC v. Nat'l Marine Fisheries Srv.*, 707 F.3d 462, 467-68 (4th Cir. 2013).

> Thus, a court must only consider the record made before the agency at the time the agency acted. The agency record does not refer simply to the facts presented to the agency but also includes the reasons given by the agency for taking the action. And a reviewing court may look only to these *contemporaneous* justifications in reviewing the agency action. As such, facts and justifications provided to a reviewing court for the first time are generally not to be considered by the court.

Id. at 467-68 (internal citations omitted). Further, the Court may not supply a reasoned basis for the agency's actions that the agency itself did not consider. *Bowman v. Transp., Inc. v. Arkansas-Best Freight Sys., Inc.*, 419 U.S. 281, 285-86 (1974).

Putting aside for a moment the issue of whether licensed vaccine stock is available currently (a fact Plaintiffs' dispute, particularly in light of a recently filed military whistleblower complaint), DoD issued an order to receive a fully licensed vaccine at a time that no licensed vaccines were available, and the only vaccination options were EUA vaccines. A finding of illegality is clearly supported: (1) there is no interchangeable vaccine listed on the FDA website; (2) Plaintiffs have only been offered EUA labeled vaccines (*see* Exhibits 6-12); and (3) the "COMIRNATY-labeled" vaccines now being offered to servicemembers are not manufactured in

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> U.S.C. § 1107a(a)(1). Rather, the DoD argues that once the FDA licensed Comirnaty, all EUA-labeled vials essentially became Comirnaty, even if not so labeled. ECF No. 45 at 60:1-3. Thus, the DoD argues, the "product" injected is a chemical formulation that has received full FDA licensure—not merely an EUA—so § 1107a does not apply. *Id.* at 65:1-6.8

Doe #1-#14 v. Austin, No. 3:21-CV-1211-AW-HTC, 2021 WL 5816632, at *5 (N.D. Fla. Nov. 12, 2021).

accordance with the approved supplemental BLA (*see* Exhibits 1-2). In short, as admitted by Defendant, COMIRNATY was not available at the time of the order, there was no FDA approved substitute, COMIRNATY and BioNTech vaccines remain as legally distinct as they were at the time FDA issued its license decision for COMIRNATY. Thus, the order plainly violated the APA at the time of its inception.

Unlawful orders do not suddenly become lawful. Contrary to Defendant's assertions, the only way DoD's order could be mooted is if it were countermanded by a subsequent order or found unlawful in another case, because if the order was illegal at its inception, it cannot hold any legal force. *See, e.g., Doe*, 341 F. Supp. 2d at 17 ("when agency regulations are unlawful, the ordinary result is that the rules are vacated—not that their application to the individual petitioner is proscribed.") (internal citations omitted) (citing *Nat'l Min. Ass'n v. U.S. Army Corps of Engineers*, 145 F.3d 1399, 1409 (D.C. Cir. 1998); *Dow AgroSciences LLC*, 707 F.3d at 467–68 ("a reviewing court may look only to these contemporaneous justifications in reviewing the agency action.") (citing *Sec. & Exch. Comm'n v. Chenery Corp.*, 318 U.S. 80, 87-88, 63 S. Ct. 454, 467-68, 87 L. Ed. 626 (1943)). Arguing that licensed vaccine stock is now available does not cure the deficiencies that existed when DoD issued its order.

Defendant also attempts to argue that 10 U.S.C. § 1107a is not applicable to DoD's mandate, because the mandate only requires vaccination with licensed vaccines. However, at the time the order was issued, no licensed vaccines were available. Moreover, as discussed below, there have been clear attempts to disguise EUA products as licensed products. Accordingly, the order does violate § 1107a, because it knowingly directed service members to comply with a vaccination order using EUA vaccines.

As such, because the order was impossible to follow at the time of its issuance, the order is unlawful. Subsequent actions, short of reversing the order, do not moot the issue of its propriety under the APA.

B. Availability of COMIRNATY Now Does Not Remedy the Lack of COMIRNATY at the Time of the Order

Compounding the straightforward APA issue raised by Plaintiffs in this case is a puzzling argument put forward by the Government. Namely, the Government argues that whatever the situation may have been in August 2021, the COMIRNATY vaccine is now available and that Plaintiffs' persisting refusal to not take it constitutes a violation of a lawful order and renders the case moot. Accordingly, Defendants argue that adverse disciplinary and administrative action is warranted. This suggestion is directly contradicted by the law, because Courts "consider the record made before the agency at the time the agency acted, so post-hoc rationalizations ... have traditionally been found to be an inadequate basis for review." *Roe*, 947 F.3d at 220–21 (cleaned up) (citing *Dow AgroSciences LLC*, 707 F.3d at 467–68 (quoting *Citizens to Preserve Overton Park v. Volpe*, 401 U.S. 402, 419, 91 S.Ct. 814, 28 L.Ed.2d 136 (1971)). And while a court "will uphold a decision of less than ideal clarity if the agency's path may reasonably be discerned," in reviewing an agency action, it "may not supply a reasoned basis for the agency's action that the agency itself has not given." *Bowman Transp., Inc.*, 419 U.S. at 285–86. In other words, agencies cannot act, and then justify their actions later or hope that illegal orders will be made legal with time. *Id.*

C. It is Not Evident That COMIRNATY Is Even Available Now

As noted above, Defendants effectively admit in their memorandum that there has been no "COMIRNATY labeled" vaccine available in the United States until May 20, 2022. But this

statement raises more problems than it allegedly solves. First, the Court should note Defendant's use of the words "COMIRNATY labeled" vaccine versus the use of the simple and accurate name of the FDA-licensed vaccine—COMIRNATY. Defendant's use of this term is likely technically correct- the vials have a label on them with the words "COMIRNATY" printed on it. But this is not the same thing as identifying the vial as COMIRNATY—that is, a vaccine consistent with the FDA licensing requirements for labeling and manufacturing. It is quite likely that Defendant consistently refuses to use the proper name because it knows that what they are offering is not in fact COMIRNATY.

To this point, there is substantial concern that vials with a "COMIRNATY" label are not licensed vaccines. As noted above, a recent military whistleblower complaint was made to Congress. One of the whistleblowers is a Coast Guard service member who details how the COMIRNATY labeled vial he was presented was not manufactured in accordance with the approved supplemental BLA. *See* Exhibits 1-2. At one point, Defendant—through counsel—offered Plaintiffs the same labeled vaccine. Concerned the same issue presented in the whistleblower complaint was now present in Defendant's suspiciously timed offer, Plaintiffs' counsel requested to view pictures of the proposed vials (especially since the USCGA and USMA Plaintiffs were likely to receive them from one location/provider). To this day, Defendants have refused to comply with this request, creating further, warranted suspicions. Exhibits 3-4.

III. The Ends Do Not Justify the Means: Defendant Paradoxically Cites the Severity of the Disease But Has Not Implemented the Simple Step of Getting a Presidential Waiver

Defendant argues that the pandemic is dangerous to the extent that the most stringent standards must be used to combat the deadliness of the disease.[6] Yet, despite the alleged severity of COVID-19, the Government has elected to not pursue the statutorily provided mechanism for requiring compliance with EUA vaccines – a straightforward Presidential waiver of informed consent. Indeed, 10 U.S.C. § 1107a provides a clear and simple mechanism for carrying out the exact kind of action that Defendant argues is necessary. Thus, Defendant's paradox is laid bare: the disease is bad enough to warrant action that involves violating Congressionally established service members' rights, but apparently not severe enough to warrant utilization of the proper mechanism.

Moreover, this case is not a challenge to the military's long history of vaccinations, nor to DoD's general ability to order compliance with vaccine, or a dismissal of the dangers that COVID-19 has presented since its arrival in March 2020. This case challenges DoD's recent

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[6] Plaintiffs readily recognize the dangers of COVID-19. But the exact scope of its severity, and of the Governments methods to combat it, are matters of open debate. Contrary to Defendants assertions, there is no way of knowing how many people have died from COVID-19, because of the incompetence of the CDC record keeping. "Right now we're still recording it and the great thing about having forms that come in and a form that has the ability to mark it as COVID-19 infection, the intent is right now that if someone dies with COVID-19 we are counting that as a COVID-19 death." Donald Trump Coronavirus Task Force Briefing April 7 (Apr. 7, 2020), https://www.rev.com/blog/transcripts/donald-trump-coronavirus-task-force-briefing-april-7.

Other examples demonstrate how difficult it is to track and identify causes of death during a pandemic. A December 16, 2021 article in MedPage Today highlighted the pressure on physicians to either add or remove COVID-19 from a family member's death certificate. A family may want it added in order to receive FEMA money for funeral services (~$9,000). *See* Beane, Kim, *Are COVID-19 Death Certificates Reliable?*, Nat. L. Rev. (June 7, 2022), https://www.natlawreview.com/article/are-covid-19-death-certificates-reliable (last visited Aug. 31, 2022).

pattern of abuse in ordering service members to take unlicensed vaccines. The military has discretion to choose the methods for dealing with COVID-19. However, once it chooses a method, it must follow the prescribed processes for implementing it—that the ends justify the means is not a suitable rationale. As stipulated in multiple rounds of bipartisan Congressional law on the matter, DoD is not permitted to "jump the gun" in ordering compliance with vaccines that have not been fully vetted. *See* 10 U.S.C. § 1107a(1) ("In the case of the administration of a product authorized for emergency use under section 564 of the Federal Food, Drug, and Cosmetic Act to members of the armed forces, the condition described in section 564(e)(1)(A)(ii)(III) of such Act and required under paragraph (1)(A) or (2)(A) of such section 564(e), *designed to ensure that individuals are informed of an option to accept or refuse administration of a product*, may be waived only by the President only if the President determines, in writing, that complying with such requirement is not in the interests of national security.")(emphasis added); *see also* 10 U.S.C. § 1107 (the predecessor statute enacted by Congress to apply to investigational products).

By Congressional design, a service member's consent is required for DoD use of EUA or other unlicensed vaccines, and an order that requires vaccination of this type without consent is contrary to law. DoD's flagrant and repeated violations are troublesome. DoD might have good intentions—the COVID-19 pandemic was a formidable threat – but such instances do not give DoD a free hand to blatantly circumvent requirements set down in Congressional statute. *See, e.g., Doe v. Rumsfeld*, 341 F. Supp. 2d 1, 19 (D.D.C. 2004) ("Congress has prohibited the administration of investigational drugs to service members without their consent. This Court will not permit the government to circumvent this requirement. The men and women of our armed forces deserve the assurance that the vaccines our government compels them to take into their

bodies have been tested by the greatest scrutiny of all—public scrutiny. This is the process the FDA in its expert judgment has outlined, and this is the course this Court shall compel FDA to follow.").

IV. DoD's Mandate is Not Saved by FDA's Improper Decisions

A substantial amount of confusion is created by Defendant's attempts to justify the errant position that all or some of the EUA vaccines are actually licensed products. In support of this Defendant puts forward arguments and documentation to suggest that vaccines can be EUA and licensed products concurrently, that vaccines created under EUA conditions can be retroactively converted and reclassified as BLA vaccines, and that FDA is authorized to both convert EUA vaccines into BLA vaccines based on vague "enforcement authority" that overrides labeling requirements and Congressional protections for service members. Defendant is incorrect on all counts.

A. Vaccines Cannot Simultaneously Be EUA and Licensed Products

The vaccines that Plaintiffs are being ordered to take are EUA vaccines, not licensed vaccines. In law, EUA vaccines are mutually exclusive from licensed products. They are "legally" distinct, and similarly have different formulations. This is apparent from the BLA letter the FDA issued to Pfizer, noting that COMIRNATY and the EUA Pfizer-BioNTech vaccines were legally distinct products.[7]

[7] *See* U.S. Food & Drug Admin., BioNTech Manufacturing GmbH Biologics License Application Approval (Aug. 23, 2021), https://www.fda.gov/media/151710/download (last visited Jan. 3, 2022); U.S. Food & Drug Admin., Letter of Authorization – Pfizer-BioNTech (reissuing authorization) (June 17, 2022), https://www.fda.gov/media/150386/download (last visited June 21, 2022); U.S. Food & Drug Admin., Letter of Authorization – Pfizer-BioNTech (reissuing authorization) (July 8, 2022).

To get around this insurmountable problem, Defendant argues that all EUA vaccines can be treated as licensed product. Defendant states:

> DoD relied on this FDA determination, as well as FDA guidance that health care providers may "use doses distributed under the EUA to administer the vaccination series as if the doses were the licensed vaccine." Ex. 1, Acting Assistant Secretary of Defense Memorandum. This is consistent with the text and purpose of § 1107a.

Def. Resp. at 27. This argument boils down to a "close enough for government work" standard that is not present in the statute. This is contrary to federal statutes and relies on an unsupported and deliberately confused reading of FDA's "enforcement authority." In fact, the legality of Defendant's position is clearly contradicted by FDA's own findings and materials.

First, the Government's assertion that the Pfizer- BioNTech COVID-19 EUA vaccine was approved as "licensed" is false. In fact, the only vaccine that has been licensed to date is BioNTech's COMIRNATY vaccine. That vaccine was, at the time of its licensing, legally distinct and separate from the Pfizer-BioNTech vaccine, and it continues to be distributed under the terms of an Emergency Use Authorization. *See* Am. Compl. at ¶ 34.

Moreover, as noted in both the government's memorandum and in the affidavit by Peter Marks, Director of the Center for Biologics Evaluation and Research ("CBER"), FDA, the two vaccines are formulaically distinct as well. As summarized by Mr. Marks:

> While FDA determined Comirnaty and the Pfizer-BioNTech Covid-19 vaccine are medically interchangeable, there are legal distinctions between BLA-approved and EUA-authorized products. For example, products approved under BLAs are required to have the labeling that was approved as part of the BLA, whereas products authorized under the EUA would have the EUA labeling, and there may also be differences in manufacturing sites for the BLA and EUA vaccine. *Both the EUA and BLA processes have required the sponsor to identify specific facilities that will manufacture the vaccine.*

Defendants Exhibit 41-2 at 6-7 (emphasis added).

FDA continues to state that the COMIRNATY vaccine has no comparators on the market with which it is interchangeable. *See* FDA Purple Book, https://purplebooksearch.fda.gov/productdetails?query=125742; Exhibit 22. Since issuing its initial licensing decision, FDA has continued to reissue the EUA for the Pfizer-BioNTech vaccine, with the latest EUA issued on July 8, 2022.[8] The upshot of this is that as of July 2022, the FDA still maintained there was no "adequate, approved, and available alternative to this product." Indeed, as of the initial filing of this case, on the FDA "Vaccine Finder" website, COMIRNATY was not available in the United States.[9]

Accordingly, every document produced by FDA treats EUA and licensed vaccines as distinct products. Despite this, Defendant DoD and the FDA attempt to play word games that contradict their own literature. Nowhere is this clearer than in Mr. Marks' statement, wherein he calls the products "interchangeable." But he is directly contradicted by FDA literature, which notes (and has noted from the first day of its licensure) that COMIRNATY has no interchangeable product. *See* FDA Purple Book, https://purplebooksearch.fda.gov/productdetails?query=125742 (last visited Aug. 31, 2022); Exhibit 22. Moreover, FDA's procedure for establishing interchangeability has not been invoked. The only conclusion is that Mr. Marks intended the word to have its plain, generic definition, rather than its legal or regulatory definition. In short, it is evident that FDA and DoD decisions are based on absurd contradictions and loose, arbitrary language.

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[8] U.S. Food & Drug Admin., Letter of Authorization – Pfizer-BioNTech (reissuing authorization) (June 17, 2022), https://www.fda.gov/media/150386/download (last visited Jun. 21, 2022).

[9] *See* Ctrs. for Disease Control and Prevention, https://www.vaccines.gov/search/, (last visited Aug. 31, 2022). Notably, while this site now shows COMIRNATY, it nonetheless apparently distinguishes between COMIRNATY and the Pfizer vaccine.

More critically, Defendant cannot identify any authority that permits FDA to treat EUA vaccines as licensed products, or to suddenly adopt the general definition of a critical phrase over its prescribed regulatory meaning. This is because EUA and licensed products inhabit roles that are mutually exclusive of one another. By continuing to label, re-approve, and produce vaccines as EUA products, FDA has affirmed that the COVID-19 vaccines available to Plaintiffs are still EUA vaccines. Defendant cannot then turn around and insist that they are also licensed vaccine products. Such action exemplifies the terms "arbitrary" and "capricious."

B. FDA Cannot Retroactively Convert EUA Lots into Licensed Lots, and FDA's Approach to Vaccine Labeling is Contrary to Federal Law

Another curious aspect of Defendant's contention that EUA vaccines can simultaneously exist as EUA products and licensed products is that some lots of EUA vaccines were automatically converted into licensed product lots by FDA.[10] The Government has even attempted to assert that the labels on vials does not accurately reflect the licensed status of vaccines. Absent accurate labeling, it is unclear how Defendant intends to identify between EUA vaccines and BLA vaccines. To cap off this bizarre rationale, there is zero authority cited for this transformative power beyond a vaguely cited "enforcement authority." The attempt to justify actions by citing a vague "enforcement authority" is exactly the kind of arbitrary and capricious action prohibited under the APA.

As admitted in Defendant's exhibit from Peter Marks, FDA "exercis[ed] its enforcement discretion with respect to certain labeling requirements, in that FDA is not taking enforcement with respect to vials that bear the EUA label" for certain lots that had subsequently been

[10] This suggestion that some, but not all, EUA vaccine lots can be retroactively converted into fully licensed vaccines directly contradicts Defendant's argument that all EUA vaccines are now also licensed.

approved to produce BLA licensed vaccines. Exhibit 2 at 41-2 at 6-7. Apparently, FDA is claiming that by simply electing not to enforce legally mandated licensing requirements, FDA retroactively "licensed" certain lots of EUA vaccines as BLA vaccines.[11] Incredibly, FDA is stating that it reclassified EUA vaccines into licensed products without any shred of statutory authority.[12]

This loose approach to licensing is problematic.[13] First, FDA licensure simply does not retroactively apply to vials shipped before BLA approval. *See* 21 U.S.C. § 355(a) ("No person

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[11] Defendant's exhibits include this report, which states that:

> Upon CBER's request inquiring about what BLA-compliant EUA-labeled lots may be available for use upon licensure of COMIRNATY, the Applicant submitted information listing which lots they considered to be manufactured according to the BLA. To address the issue of these lots not bearing the vial label associated with BLA approval, CBER worked with the Applicant to develop a Dear HCP letter to be included with lots considered by CBER to be BLA-compliant. This letter explained that some lots labeled for EUA use were also considered BLA-compliant and refers HCP to a website for additional information. CBER requested and the Applicant agreed that only EUA-labeled lots that had also undergone CBER lot release according to the BLA would be considered BLA-compliant and listed at the website included in the Dear HCP letter.

Defendant's Exhibit 42-2 at 51.

[12] Defendant has tried this sleight of hand before, without success. *See Doe #1-#14 v. Austin*, No. 3:21-CV-1211-AW-HTC, 2021 WL 5816632, at *5–6 (N.D. Fla. Nov. 12, 2021). More importantly, Defendant cannot say whether any Plaintiff or any service member has even received these lots of transformed vaccine. And finally, Defendant and FDA have zero authority to declare that a vial of vaccine marked EUA is not EUA, and thus makes mandatory vaccination with that vial okay under 10 U.S.C. § 1107a. This would seem to be completely inconsistent with the APA requirement that government action not be arbitrary or capricious.

[13] The conflation of the various licensing types is apparent throughout the response brief. For example, Defendant states:

> In other words, DoD has COMIRNATY-labeled vaccine, BLA-compliant doses of the Pfizer-produced vaccine, and EUA doses that are interchangeable with the licensed vaccine. See Ex. 4, Rans Decl. ¶ 19 ("The DoD has received hundreds of thousands of

shall introduce ... into interstate commerce any new drug, unless an approval of an application [for FDA licensure] is effective with respect to such drug." (emphasis added)). Thus, as a legal matter, vaccines sent before August 23, 2021—and vaccines produced after August 23, 2021, in unapproved facilities—remain "product[s] authorized for emergency use under section 564 of the Federal Food, Drug, and Cosmetic Act." § 1107a(a)(1). Section 1107a's explicit cross-reference to the EUA provisions suggests a concern that drugs mandated for military personnel be actually BLA-approved, not merely chemically similar to a BLA-approved drug. FDA's decision to ignore this thus contravenes federal statute.

Equally as troubling is the apparent inability of DoD to identify which vaccines are EUA, and which vaccines are licensed. The FDA, the agency entrusted with ensuring that medical products are properly marked and labeled, at the request of DoD, has created a situation where the labeling on COVID-19 vaccines cannot be trusted. The FDA's COMIRNATY approval letter says that the labeling on COMIRNATY vials "must be identical" to what Pfizer submitted in its application, but this label does not appear to be identical to an EUA label. And federal regulations require that the FDA commissioner initiate license revocation proceedings if he determines that a licensed product is "misbranded with respect to any [of its intended uses]" or "fails to conform to the applicable standards established in the license ... designed to ensure the continued safety, purity, and potency" of the product. 21 C.F.R. § 601.5(b)(1)(iv), (vi). These provisions clearly prohibit distributing a fully licensed drug with an EUA-specific label and

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> Pfizer-BioNTech BLA-compliant, EUA-labeled COVID-19 vaccine doses and continues to use them.")

Def. Resp. at 28.

package. But the FDA now states with respect to DoD's use of COVID vaccine that it has effectively licensed misbranded vials of Pfizer's product.

In short, the FDA's approach towards EUA vaccines is contradictory and nonsensical. Vaccine licensing is not Schrödinger's cat – EUA vaccines cannot be both licensed and unlicensed at the same time. FDA cannot attempt to retroactively convert EUA vaccines into licensed vaccines in the complete absence of statutory authorization (and allow an end run of Congressional protections for service members), nor can FDA just decide based on "enforcement authority" to ignore licensing distinctions. This is the very definition of arbitrary and capricious action precluded by the APA.

Accordingly, DoD cannot conceivably base a vaccine mandate on such a flawed, unsupported set of FDA determinations. Defendant readily admits that its decision was predicated on the above decisions of the FDA. Def. Resp. at 27.

V. The Constitutional Harm is Sufficiently Pleaded and is Readily Apparent

Plaintiffs' First Amended Complaint plainly includes a cause of action pleading "a Violation of Plaintiff's Constitutional Right to Procedural Due Process Under the Fifth Amendment." First Am. Compl. at 20. Plaintiffs plead this violation of their Fifth Amendment rights in conjunction with their claim regarding the violation of DoD and its component services' own regulations.[14]

[14] For the purposes of the reply brief, Plaintiffs have focused the Court's attention on the DoD's violation of Congressional statute – namely 10 U.S.C. § 1107a. Nonetheless, Plaintiffs underscore the additional failure of DoD to follow its own regulations which require evaluation of a service member's immunity and medical history. Defendant's Response reflects a misunderstanding - whether prior COVID-19 infection or natural immunity would "automatically" result in exemption under AR 40-562 is not the issue. Def. Resp. at 29. Instead, the regulation simply and clearly states that an assessment of natural immunity must be done. No such assessment has been attempted on any Plaintiff in this case.

Moreover, as found by the Fourth Circuit, DoD's a failure to follow its own regulations deprives affected service members of their Fifth Amendment rights. *Bluth v. Laird*, 435 F.2d 1065, 1071 (4th Cir. 1970). "The Due Process Clause is implicated [when] an individual has reasonably relied on agency regulations promulgated for his guidance or benefit and has suffered substantially because of their violation by the agency." *United States v. Caceres*, 440 U.S. 741, 752-53 (1979).

At this stage, Plaintiffs have pleaded a clear-cut case of an APA violation by the DoD and its component services. DoD has failed to abide by congressional statute and DoD regulations. This failure directly implicates the Due Process rights of the service members affected, including each and every Plaintiff in this case.

VI. Irreparable Harm is Clearly Impending Absent a Preliminary Injunction

The treatment of the USCGA cadets is offered as an indication of the potential irreparable harm awaiting Plaintiffs who are also under Defendant's control. The USCGA Cadets were ordered, without reasonable notice, to be posted to their "homes" as a temporary duty location, notwithstanding the fact that at least one of the cadets did not have a "home" to report to and was reduced to living in his car for four days.[15] Exhibits 5; 13-14; 16-21.

Moreover, Defendant and its component service the Coast Guard made no provisions to provide the Cadets with the required temporary duty per diem allotment, nor did Defendant provide the cadets with travel orders or travel funds. Exhibit 5, 13-15. The cadets were ordered to pay for their travel expenses, in at least one case across the country, out of their own personal

[15] The question of whether ordering servicemembers to duty and forced accommodation in private residences raises an interesting question under the Third Amendment, U.S. Const., but Plaintiffs do not intend to address it here.

funds. No provisions to this date have been made for reimbursing them, providing them with the required per diem, or allocating access to any of the other required elements for an assignment on temporary duty. Exhibit 15 at 5. This has directly impacted the cadets' finances (for example, one cadet's family had to stop renting out a room, thus denying the family a critical source of income.) Exhibit 5. Upon inquiring as to how they could keep up with their ordered requirements, the cadets were informed that they were expected to keep up with training, but that no provisions would be made for their academic upkeep. Exhibit 15 at 2-4. Indeed, any efforts undertaken by the USCGA cadets to stay current with academic expectations would rest solely on the cadets. *Id.* The other Plaintiffs have exhausted exemption options and are being funneled towards impending separation. Defendant makes it clear that it and its component services perceive Plaintiffs as a threat to be eliminated. Def. Resp. at 32; Exhibits 16-21.

The permanent damage caused by these actions is clear. Plaintiffs are suffering direct economic harm and are being placed in compromising situations that threaten their physical well-being, as well as being faced with imminent disciplinary and administrative action.

IV. CONCLUSION

For these reasons, Plaintiffs request this Honorable Court preliminarily enjoin Defendants from enforcing their unlawful orders and taking any adverse action against Plaintiffs for failing to obtain the vaccine pending final resolution of this case.

Respectfully submitted,

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